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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,543	08/15/2001	Raymond F. Cracauer	FORS-06495	2204
23535	7590	07/26/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			NAGPAUL, JYOTI	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/930,543	<b>Applicant(s)</b> CRACAUER ET AL.	
	<b>Examiner</b> Jyoti Nagpaul	<b>Art Unit</b> 1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

***Claim Interpretation***

With respect to claim 11, in the art, the definition of reaction support usually refers to when a DNA molecule is attached or bounded to during the various steps of DNA synthesis and/or when the DNA molecule is being cleaved at the end of the DNA syntheses process. The applicant defines a reaction support as a fixed surface to support three or more synthesis columns. (Lines 13-14, page 3) There is indefinite and unclear use of terminology therefore the examiner has used the definition of the terminology of reaction support which is a fixed surface to support three or more synthesis columns.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

**Claim 1** is rejected under 35 U.S.C. 102 as being anticipated by Zelinka.

Zelinka teaches a automated system comprising of a closed system nucleic synthesizer and a cleavage and deprotect component. Zelinka further teaches a controlled gene synthesizer for programmably synthesizing selected nucleotide sequences. The apparatus operates to sequentially wash and dry the contents of the cell, expose nucleotide reaction sites, add and couple bases at the reaction sites and cap or protect the reaction sites by a robotic component. Some of the functions related to operator programming of a desired DNA coupling sequence include selecting various ones or combinations of the individuals basses; adding the selected bases or combinations to the reaction cell with appropriate preparation and washout step;

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performing the washing of the reaction cell for the next base addition. (Lines 61-3, Col. 17-18) Zelinka describes to each base addition includes refilling of syringes, performing a pyridine wash and nitrogen blow down of the reaction cell, capping the ends of the nucleotide sequences, cell temperature control and resetting the elapsed time counter. Zelinka also discusses means for heating the reaction cell to promote the growth process. (Lines 56-57, Col. 2) The temperature controller provides the operator with pertinent temperature information as it relates to the reaction cell. The temperature controller generally monitors the temperature of the reaction cell and which is heated by an epoxy encapsulated thin film heater element that is wrapped around the reaction cell. The temperature is set and read via a set/read switch. (Lines 55-68, Col. 5) Zelinka describes this process continues until desired growth oligonucleotide is chemically separated from the solid support material. (Lines 22-20, Col. 2) Zelinka describes a fluid circuit exists from source to waste at any time reagents are being transferred. Zelinka teaches isolation is achieved via a valve body V17 that acts as a selector valve for the solvent bottles. (Lines 52-55, Col. 11) The enablement of the valve body V17, only one or desired simultaneous combination of the solvent/reagents is selected and directed to valve body V26. Depending on the position of valve body V26 the liquid is again selectively directed either through reaction cell 14 to valve body V27 and then to collection or waste; or is blocked from flowing through cell 14 and in which case a nitrogen or argon gas purge is directed from the top of the cell 14. (Lines 57-65, Col. 11, Refer to Fig. 6) Therefore, comprising of a closed system.

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Thus, it reasonably appears that Zelinka describes or discloses every element of the claim and therefore anticipates the claims subject to this rejection.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 2-3,6-9, and 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelinka in view of McGraw.

McGraw teaches apparatus and method for an automated synthesis of DNA segments utilizing multiple reaction columns (11). (Refer to Fig. 1B) The device enables the parallel synthesis of large number of different oligonucleotide sequences of different lengths. McGraw discusses a reaction chamber that contains one or more reaction columns in which a particular oligonucleotide sequence is synthesized. (Lines 66-69, Col. 1) McGraw teaches when the synthesis of all oligonucleotides is complete; the reaction columns are removed from the instrument. The DNA products may then be cleaved from their supports and subjected to conventional deprotection. Then may also be purified. (Lines 65-68, Col. 8) A personal computer is used to control the sequence through which chemicals are added to the reaction columns to produce the desired oligonucleotide in each column. The computer acts to control the movement of outlet, the operation valves, the timing of reactions, in short, the entire process. (Lines 55-65, Col. 4)

Zelinka fails to describe a synthesizer configured for parallel synthesis of nucleic acid molecules in three or more reaction chambers.

It would have been obvious to one of the ordinary skill in this art at the time of the invention by applicant to modify the system of Zelinka to include the feature of McGraw such that a synthesizer configured for parallel synthesis of nucleic acid molecules in three or more reaction chambers to increase the number of oligonucleotides produced each day therefore causing the synthesizer to be more efficient. It would also have

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been obvious to one of the ordinary skill in this art at the time of the invention by applicant to modify the system of Zelinka to include the feature of McGraw such that the optimized reaction temperature being in the range of about 20 degrees C to about 60 degrees C because the operator is capable of setting the range to heat the cuvettes at any temperature to ensure accelerated growth of the oligonucleotides.

**Claims 4 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelinka in view of Zanzucchi.

Zanzucchi teaches a sample tracking software configured to associate sample identification tags with samples that are processed and it is also configured to receive further synthesis request information from a user. In Zanzucchi's teachings, the apparatus includes a computer, which the computer is programmed to give instructions to a microlaboratory disc and to record results obtained therefrom. (Lines 65-4, Col. 3-4) Zanzucchi further teaches sample identification means, the sample is identified with a bar code or other high density code affixed to the loading capillary tube. (Lines 61-63, Col. 5)

Zelinka fails to teach a sample tracking software configured to associate sample identification tags and to receive synthesis request information from a user.

It would have been obvious to one of the ordinary skill in this art at the time of the invention by applicant to modify the system of Zelinka to include the feature of Zanzucchi such that a sample tracking software configured to associate sample identification tags and to receive synthesis request information from a user in order to

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monitor the samples during the various steps of DNA synthesis causing the process to continue more efficiently.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN

*Jyoti Nagpaul*

*primary examiner*  
*AU 1743*